DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

May 14, 2002

Our Submission Tracking Number: BL 103756/5001

Mr. Harry Malyska
Micro Typing Systems, Inc.
1295 S.W. 29th Avenue
Pompano Beach, FL 33069

Dear Mr. Malyska:

Your Biologics License Supplement for Blood Grouping Reagent Combination Kit to include the manufacture of a "Monoclonal Rh Phenotype Card", has been approved effective this date. Each Monoclonal Rh Phenotype Card contains, sequentially, the following monoclonal Blood Grouping Reagents: Anti-D, Anti-C, Anti-E, Anti-c, Anti-e, Control.

Under this license you are hereby authorized to introduce or deliver for introduction into interstate commerce the Monoclonal Rh Phenotype Card using the gel card system manufactured at Micro Typing Systems, Inc. under U.S. License No. 1177.
Changes to the product, source of materials, production process, location of production process, equipment, facilities, or responsible personnel are required to be reported to FDA as specified in Title 21 Code of Federal Regulations (CFR) Section 601.12. In addition, any significant decrease in the potency or other change in this product should be reported promptly to the Center for Biologics Evaluation and Research.

You are requested to submit samples of future lots of this product together with protocols showing results of all applicable tests. No lots of product shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research (CBER).

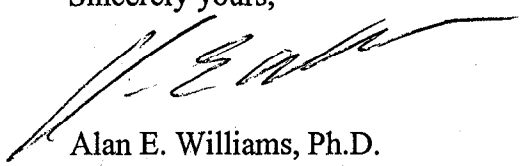
The dating period for this product shall be 18 months from the date of manufacture when stored at 1-8° C. The date of manufacture shall be defined as the date the gel cards are filled.

All adverse reports should be submitted according to 21 CFR 803 to the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847-3002.

Please submit three (3) copies of final printed labeling at the time of use accompanied by FDA Form 2567 with completed implementation information. In addition, you may wish to submit your proposed introductory advertising and promotional campaign. If so, please submit three (3) copies of the proposed material in draft form with Part I of the FDA Form 2567/2253 to Food and Drug Administration, CBER, Division of Case Management, Advertising and Promotional Labeling Branch (APLB), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by CBER. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2253 to APLB. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

It is recommended that a copy of this letter be available for review at the time of FDA inspections.

Sincerely yours,



Alan E. Williams, Ph.D.
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Office of Blood Research and Review
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